

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Hamilton et al. Confirmation No.: 8120
Application No.: 10/628,915 Group Art Unit: 3768
Filed: July 29, 2003 Examiner: Lawrence N. Laryea
Title: CARDIAC DIAGNOSTICS USING WALL MOTION AND PERfusion CARDIAC
MRI IMAGING AND SYSTEMS FOR CARDIAC DIAGNOSTICS

DECLARATION OF DR. CRAIG HAMILTON PURSUANT TO 37 C.F.R. 1.131

Sir:

I, Craig Hamilton, hereby declare and say that:

1. I am one of the inventors of the subject matter of the claims rejected in the Office Action mailed March 8, 2007, for the above-referenced application.

2. Prior to September 19, 2002, we conceived and reduced to practice the invention claimed in the rejected claims.

3. In support of the above statement of paragraph 2, I note that the instant application claims priority to two provisional applications, one filed July 29, 2002, and one filed October 28, 2002.

4. In further support of the statement at paragraph 2, I am attaching a copy of an email dated June 17, 2002, with certain content redacted. This email is from Rodney Moore, Ph.D., the then Assistant Director of the Office of Technology Asset Management of Wake Forest University School of Medicine to a patent attorney at the patent law firm of Myers, Bigel, Sibley & Sajovec, P.A. This email describes at paragraph 5, the simultaneous display of wall motion and perfusion data of the claimed invention.

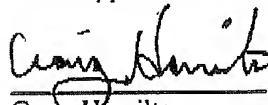
5. In further support of the statement at paragraph 2, I am attaching a screen shot of an mpeg movie dated September 9, 2002, displaying wall motion and perfusion. The date

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Application No.: 10/628,915
Filed: July 27, 2003
Page 2

the mpeg was created is embedded in the header of the MPEG file: MPEG stream encoded by UCB Encoder (mpeg_encode) v1.5b on Mon Sep 9 07:56:04 2002.

6. I am also attaching a copy of a print out of a docketing summary from Myers Bigel Sibley & Sajovec, P.A., indicating the date that the file for the second provisional application was opened at the patent law firm, as indicated with a "date created" of 30 July 2002. I am also attaching a copy of one page of a redacted letter from the patent attorney dated October 4, 2002, sending the working draft of the patent application to me for review. This second provisional application was diligently filed with the USPTO on October 28, 2002.

7. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true. I further declare that these statements were made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

6-6-07
Craig Hamilton Date

Sibley, Kenneth

From: Rodney Moore [rmoore@wfubmc.edu]
Sent: Monday, June 17, 2002 4:52 PM
To: Sibley, Kenneth
Subject: Cardiac MRI patent

Ken,

I've talked with the inventors about potentially patentable material in their software. I would like to talk to you about it, but I thought I would put it in writing first so that you would have something to refer to. I realize that some of these ideas are pretty weak, but together, perhaps, they will be enough to protect our product.

First a couple of definitions. A view shows a particular "slice" through the heart. There can be as many as 8 views. Doses refers to doses of dobutamine, which is used to increase heart rate. Therefore, there are $8 \times 8 = 64$ view/dose combinations at which cine loops are recorded. Using this software, the physician only looks at one particular view at all doses, or all views at one dose. Viewing all of the data simultaneously is just too confusing.

Here are the specific elements that seem unique to our software:

1. Brightness/contrast settings, once set for a particular view at a single dose, are propagated to all doses at that particular view.
2. Cropping settings and magnification, once set for a particular view at a single dose, are propagated to all doses at that particular view.
3. Images for a particular cine loop are automatically verified as being ready for display as they arrive from the scanner (rather than the physician having to constantly query the computer until the images arrive).
4. Note that dobutamine raises the heart rate (causes stress) which can reveal otherwise hidden pathology. The Cardiac MRI software performs temporal interpolation on the images to insure that cine loops representing the heart at different doses of dobutamine appear to be beating in unison (for easier comparison) rather than displaying hearts beating at different rates.
5. We can simultaneously display wall motion and perfusion data at multiple views. The heart is shown in the most stressed state (to reveal wall motion defect) along side an image of the progress of the perfusion of an injected contrast agent (to show the part of the heart that is receiving inadequate blood flow because of an occluded artery). The position of the wall motion defect and poor perfusion should correspond to one another.
6. The software is capable of maintaining all of the data in memory at one time so that the physician can switch instantaneously between views.

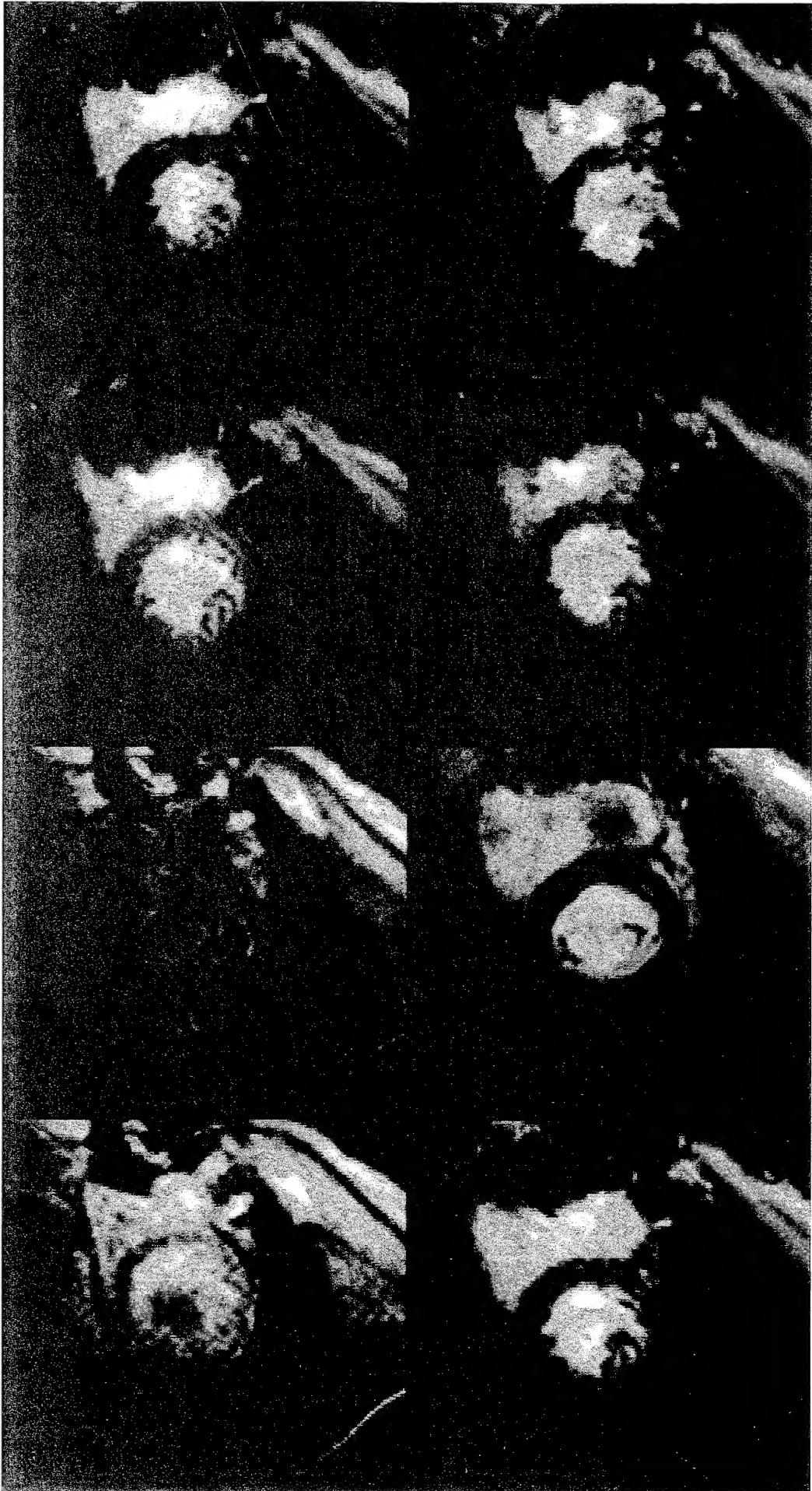
Hopefully we can talk about these ideas in the next few days.

Thanks,
Rodney

Rodney J. Moore, Ph.D.
Assistant Director, Office of Technology Asset Management
Wake Forest University School of Medicine
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ÍÍÍ³@ÍÍÍÿyàÍÍÍ²MPEG stream encoded by UCB Encoder (mpeg_encode) v1.5b
on Mon Sep 9 07:56:04 2002
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Country Application

Tuesday, July 30, 2002

Case Number: 09151.00026PR

Country: US SubCase:

Client: Wake Forest University

United States of America

Case Type: PRO

Application Status: Unfiled

Application Number:

Filing Date:

Publication Number:

Publication Date:

Patent Number:

Issue Date:

Parent/PCT Number:

Parent/PCT Date :

Parent Issue Number:

Parent Issue Date :

Agent:

Expiration Date:

Agent Reference No.:

PTA: 0

Tax Schedule: LE

Confirmation #:

Remarks: FOREIGN FILING CALL-UPS NEEDED

User ID: agilbert

Date Created: 30-Jul-2002

Last Update: 30-Jul-2002



October 4, 2002

Ref: 9151-26PR and 27PR
Dept:Date: 04OCT02 SHIPPING \$9.27
Wgt: 1 LBS SPECIAL \$0.23
HANDLING \$0.00

TOTAL \$9.50

PO Box 37428
Raleigh, NC 27627

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TRACK: 6018 7715 0117

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P: (919) 854-1400
F: (919) 854-1401Re: *Cardiac Diagnostics Using Time Compensated Stress Test Cardiac Mri Imaging And Systems For Cardiac Diagnostics*
Our File No.: 9151-26PR; Your File No.: WFU 01-13

www.myersbigel.com

Dear Craig:

Attached please find a working draft of the above-referenced provisional patent application for your review.

It is essential that the patent application as filed be technically accurate and complete, and sets forth the best mode of carrying out your invention. Since new matter may not be added to the descriptive portion after filing, we ask that you, carefully review the draft for technical accuracy and completeness, and advise us of any suggested changes or corrections. Your changes and suggestions will be carefully considered in the preparation of the final draft.

Out of an abundance of caution, we are requesting that you confirm that the proper inventive entity has been identified for the claimed invention(s). At present, you have been identified as the only inventor. As you may be aware, inventorship is determined based upon the subject matter of the claimed invention. Generally stated, to be an inventor one must have made an actual contribution to the conception of the operative invention which is claimed. There may be joint inventorship even though the joint inventors (a) did not work physically together or at the same time, (b) did not make an equal contribution or (c) did not make a contribution to the subject matter of every claim of the patent. A worker who merely carries out the instructions of another or only provides implementing devices to carry out another's ideas where the effort to do so is the exercise of one of ordinary skill is not typically an inventor. Further, all persons listed as co-authors on an article describing or related to the invention are not necessarily inventors. Please feel free to call with any questions you may have on this issue. There is no need to respond on this matter if the inventorship is correct.

We would also like to point out that each inventor is required to make a Declaration when the application is filed in the U.S. Patent and Trademark Office, acknowledging a duty

Craig A. Hamilton
October 4, 2002
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to disclose information of which he or she is aware and which may be considered to be material to the examination of the application. "Material" in this respect is defined as information that an examiner would likely consider important in deciding whether to issue a patent.

"Material" information as defined above may possibly include devices, products, publications, etc. which are similar to your invention and which were publicly known before your invention, and it may also include any public disclosure commercial use, or offer of sale of your invention more than one year prior to the filing date of your application.

If you are aware of any information (or subsequently become aware of information) which you believe might be considered "material", it is vitally important that it be brought to our attention. We can then make a determination as to whether the information should be brought to the attention of the Patent and Trademark Office under the applicable rules. Please also be aware that the duty to disclose information continues throughout pendency of the application, until the application issues as a patent. The duty to disclose information continues throughout the pendency of the application until a patent actually issues.

You should also be aware that certain activities either in the United States or foreign countries prior to filing of the application in the United States may have a bearing on your ability to file corresponding applications in foreign countries under the applicable international treaty. These activities could include public disclosure of your invention in either written or oral form, such as published articles, theses, patents, product announcements and proposals as well as through commercial exploitation of your invention, including public demonstrations, offers to sell, and sale of products incorporating your invention.

If you would like to preserve your right to file corresponding foreign applications on this invention, we recommend that all such activities should be avoided until the U.S. application is on file.

Please let us have your comments as soon as possible. If you should have any questions, please feel free to give me a call.

Best regards.

Sincerely,



Timothy J. O'Sullivan

TJO/tb
Enclosure
cc: Mr. Spencer K. Lemons (w/ enc.)
Kenneth D. Sibley, Esq. (w/o enc.)